-- 114. (New) The introducer sheath device according to Claim 107, wherein said fluid is saline.--

REMARKS

Applicants note with appreciation that Claim 101 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. New independent Claim 104 incorporates all of the features of Claim 101. In addition, Claims 105-114 depend from Claim 104 and, at a minimum, include all of the features of same. As such, Applicants respectfully request allowance of Claims 104-114.

Claims 82, 85-87, and 96-114 are present in this application. By this amendment, Claims 82 and 101 are amended, and Claims 104-114 are added. Applicants respectfully request reconsideration in view of the above amendments and the following remarks.

I. THE CLAIMS ARE PATENTABLE OVER U.S. PATENT NO. 5,599,305 TO HERMANN ET AL.

Claims 82, 85-87, 96-98, 100 and 102 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,599,305 to Hermann et al. (hereinafter "Hermann"). This rejection is respectfully traversed.

Hermann teaches an aortic introducer catheter (70) having a first inflatable balloon (76) to provide partial occlusion of blood flow and a second inflatable balloon (78) to anchor the distal end of the catheter and, in a more particular aspect, to anchor expandable grafts and other prostheses. (Col. 10, lines 29-42; FIG. 6). Hermann further teaches a homeostasis valve assembly (18) comprising a foam insert (38). (Col. 9, lines 58-59; FIG. 3). The foam insert (38), in its uncompressed configuration, will have an open

axial lumen (52), more preferably being flared open at its proximal end (54). (Col. 10, lines 4-9; FIG. 4). As assembled, or a combination as claimed, the homeostasis valve assembly (18) comprises a compressed foam insert (38) having a reduced diameter axial lumen. (FIG. 3). Hermann teaches that when the foam insert is disposed within the assembly, the insert will be compressed sufficiently to close the lumen (52). Hermann further teaches that the resilient nature of the foam will permit the lumen to reopen as a catheter is advanced therethrough. (Col. 7, lines 50-54). Thus, the lumen (52) is opened, even when the foam insert is in its compressed state. Figure 3 clearly discloses that the compressed foam insert (38) has an axial lumen (52) with a reduced, yet present, diameter. Additionally, lumen connectors (80 and 82) are provided in order to connect the balloons (76 and 78) to suitable inflation sources, typically pressurized contrast medium. (Col. 10, lines 47-50).

Applicants disclose an introducer sheath device comprising a housing having a passageway that accommodates the passage of surgical components therein and sealing means for preventing the loss of blood from the vessel during the insertion and subsequent removal of surgical components during the surgical procedure. The sealing means comprises a sealing cavity filled with a biocompatible sealing material and such sealing material does not therein contain a pre-formed lumen. Moreover, the sealing material is self-sealing. The sealing material forms a seal around the surgical components as the components are inserted through the sealing material and removed from the introducer sheath device during the surgical procedure. Furthermore, in one embodiment of the present invention, the introducer sheath device includes at least one filling passage way,

for filling an inflatable cuff, that extends along the passageway which accommodates the passage of the surgical components.

For at least the reasons set forth above, Applicants respectfully submit that Hermann fails to disclose, teach, or suggest the subject matter of the present invention. Reconsideration and withdraw of the rejection are respectfully requested.

II. CLAIM 99 IS PATENTABLE OVER HERMANN

Claim 99 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hermann. This rejection is respectfully traversed.

Claim 99 depends from Claim 82 and, at a minimum, includes all of the features of same. As such, Claim 99 distinguishes over Hermann for at least the reasons stated above. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. CLAIM 103 IS PATENTABLE OVER HERMANN IN VIEW OF U.S. PATENT NO. 3,978,863 TO FETTEL ET AL.

Claim 103 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hermann in view of U.S. Patent No. 3,978,863 to Fettel et al. (hereinafter "Fettel"). This rejection is respectfully traversed.

Claim 103 depends from Claim 82 and, at a minimum, includes all of the features of same. As such, Claim 103 distinguishes over Hermann for at least the reasons stated above. Moreover, Fettel does not disclose, teach, or suggest all of the features of Claim 103. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

IV. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the Claims of the present invention define subject matter patentable over the references cited by the Examiner and that the application is in condition for allowance. Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the below listed telephone number.

Respectfully Submitted,

Date:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Howard Tanner et al.**		
Serial No.:	**09/108,189**	**Examiner:**	**J. Thissel**
Filed:	**July 1, 1998**	**Group Art Unit:**	**3763**
For:	**AN INTRODUCER SHEATH FOR USE DURING A SURGICAL PROCEDURE**		
Attorney Docket No.:	**23660-00611**		

MARKED-UP VERSION OF AMENDMENT AND RESPONSE

Assistant Commissioner for Patents
BOX NON-FEE AMENDMENTS
Washington, DC 20231

Dear Sir:

In response to the Office Action dated April 25, 2001, please amend the above-identified patent application as follows:

IN THE CLAIMS:

Please amend Claims 82 and 101 as follows:

82. (Thrice Amended) An introducer sheath device for use during a surgical procedure for introducing surgical components into a vessel into a patient, said introducer sheath device comprising:

a housing having a passageway that accommodates the passage of the surgical components therein;

sealing means for preventing the loss of blood from the vessel during the insertion and subsequent removal of surgical components during the surgical procedure, wherein

said sealing means comprises a sealing cavity, wherein said sealing cavity is filled with a biocompatible sealing material, wherein said sealing material does not contain a pre-formed lumen, wherein said sealing material is self-sealing, wherein said sealing material forms a seal around the surgical components as the components are inserted through said sealing material and removed from said introducer sheath device during the surgical procedure.

101. (Amended) The introducer sheath device according to Claim 82, wherein said biocompatible sealing material is a [self-sealing] gel-like material.

Please add new claims 104 -114 as follows:

--104. (New) An introducer sheath device for use during a surgical procedure for introducing surgical components into a vessel into a patient, said introducer sheath device comprising:

a housing having a passageway that accommodates the passage of the surgical components therein;

sealing means for preventing the loss of blood from the vessel during the insertion and subsequent removal of surgical components during the surgical procedure, wherein said sealing means comprises a sealing cavity, wherein said sealing cavity is filled with a biocompatible sealing material, wherein said sealing material does not contain a pre-formed lumen, wherein said sealing material is a self-sealing gel-like material, wherein said sealing material forms a seal around the surgical components as the components are inserted through said sealing material and removed from said introducer sheath device during the surgical procedure. --

--105. (New) The introducer sheath device according to Claim 104, further comprising:

positioning means for maintaining the position of said introducer sheath device in the vessel.--

--106. (New) The introducer sheath device according to Claim 105, wherein said positioning means comprises an inflatable cuff positioned at one end of said introducer sheath device.--

--107. (New) The introducer sheath device according to Claim 106, wherein said inflatable cuff is filled with a fluid.--

--108. (New) The introducer sheath device according to Claim 106, wherein said positioning means further includes at least one filling passageway for filling said inflatable cuff.--

--109. (New) The introducer sheath device according to Claim 108, wherein said at least one filling passageway extends along said passageway that accommodates the passage of the surgical components.--

--110. (New) The introducer sheath device according to Claim 104, wherein said housing comprises an outer surface and an inner surface.--

--111. (New) The introducer sheath device according to Claim 110, wherein said outer surface comprises silicon.--

--112. (New) The introducer sheath device according to Claim 110, wherein said inner surface comprises a synthetic fluorine-containing resin or a polymer.--

-- 113. (New) The introducer sheath device according to Claim 104, wherein said sealing cavity comprises an expanded housing assembly.--

-- 114. (New) The introducer sheath device according to Claim 107, wherein said fluid is saline.--